

RESPONSE

The present communication responds to the Office Action mailed September 25, 2002 for the above-identified application. In that Office Action, the examiner rejected claims 1-10 under 35 U.S.C. 112, second paragraph, claims 1-8 and 10 under 35 U.S.C. 102(b), and objected to claim 9. Further, the oath or declaration was identified as defective and the drawings were objected to.

A supplemental oath is being filed herewith in compliance with 27 CFR 1.67(a).

The Examiner objected to the drawings, indicating that the drawings must show every feature of the invention specified in the claims and that, therefore, the stem must be shown or the feather(s) canceled from the claim(s). Further drawings are being submitted herewith as well as an amended specification. (In submitting the amended specification, the applicants are enclosing a substitute specification as well as an amended specification with markings to show changes made.) Applicants submit that no new matter is being added and support for the drawings can be found at least at page 4 of the specification in the description of Figure 1. Additionally, new claims 12-19 have been added, such claims eliminating reference to a stem.

The Examiner objected to claim 9 as including a misspelling at the end of line 1. Claim 9 has been amended.

The Examiner rejected claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner expressed that the word "being" in the recitation of the bore "being formed in the flat head face" renders the claim an improper "product-by-process" claim because of the tense. Applicant respectfully disagrees with the Examiner rejection, however, claim 1 has been amended

to facilitate speedy prosecution of the present application. The Examiner further indicated that there was insufficient antecedent basis for the limitation "the locking member" in claims 6-7 and claim 9. Claim 1 has been amended to address the Examiner's concern.

The Examiner rejected claims 1-6 and 10 under 35 U.S.C. 102(b) as being anticipated by Tornier (U.S. Patent No. 5,358,526). Tornier discloses a modular prosthesis including a stem 1, a spacer 2, and a semi-spherical cap 3. In particular, the spacer 2 is made in the form of a prism 20 of which the two end faces are not parallel in order to constitute a sort of wedge. (Col. 3, lines 27-45). Tornier provides for a series of spacers of different slopes so that the inclination of the humeral semi-spherical cap 3 may be adjusted according to the clinical case. (Col. 3, lines 63-68). Applicants respectfully disagree with the Examiners assertion that spacer 2 of Tornier is a connecting member as claimed in the present application.

As discussed at least at page 4 to page 5 of the present application, the connecting member 12 is secured to the humeral head 10 by loosely fitting the flat round plate of the connecting member into the shallow bore 18 of the humeral head 10. Importantly, one degree of eccentricity is achieved by rotating the connecting member 12 until the desired offset of the second portion 16 of the connecting member 12 to the humeral head 10 is achieved. As discussed at least on page 5, another degree of eccentricity is achieved by the location of the bore eccentrically on the flat bottom surface of the humeral head; that is, the axes of the spherical head and the bore are spaced apart. Thus, referencing at least at page 6 of the present application, the eccentricity of the humeral head to a portion of the connecting member attachable to the stem may be adjusted in two different ways as provided by the connecting member. First, the bore within the humeral head is non-coaxial with the humeral head. Thus, in

selecting placement of the connecting member within the bore, a first degree of eccentricity is achieved. Second, the second portion of the connecting member is non-coaxial with the first portion of the connecting member. Thus, by rotating the connecting member within the bore, a second degree of eccentricity is achieved.

Tornier neither teaches nor suggests a modular humeral head having a bore non-coaxial with the axis of the head, thereby providing a first degree of eccentricity, a second degree of eccentricity being achieved by rotation of a connecting member within the bore, as specifically claimed in claims 1, 4-10, and 12-19.

The Examiner rejected claims 1 and 7-8 under 35 U.S.C. 102(b) as being anticipated by Camino et al. (U.S. Patent No. 6,033,439). Camino discloses a shoulder prosthesis including a humeral body element 20, a shank element 22, and a head member 48. The body element 20 can be formed integrally with, or as a separate component from the shank element 22. (Col. 4, lines 42-47). The head member 48 has a geometric axis 52 therethrough and is selectively mounted on a collar 58. (Col. 6, lines 10-12). a second geometric axis 55 extends through the center of the opening 54 and thus through the skirt 66. The second axis 55 may be coincident with the first geometric axis 52. Alternatively, the second axis 55 is spaced-apart from the first geometric axis 52. This offset positioning of the second axis 55 from the first axis 52 results in eccentric alignment of the head member 48 on the shank 20. (Col. 6, lines 23-31).

Regardless of whether the applicants agree with the Examiner's assertions regarding the Camino reference, Camino neither teaches nor suggests a modular humeral head having a bore non-coaxial with the axis of the head, thereby providing a first degree of eccentricity, a second degree of eccentricity being achieved by rotation of


a connecting member within the bore, as specifically claimed in claims 1, 4-10, and 12-19.

In light of the above, applicants respectfully submits that each of claims 1, 4-10, and 12-19 is in condition for allowance. As these are the only claims pending in the application, prompt issuance of a Notice of Allowance in this case is courteously solicited.

If any additional fees are required to enter the present amendment, Applicant hereby authorizes the Office to charge our deposit account, Deposit Account No. 061910. If the Examiner feels that prosecution of the present application can be materially advanced by a telephonic interview, the undersigned would welcome a call at the number listed below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. A modular shoulder prosthesis for replacement of the humeral head of a humerus, comprising:

a stem having a distal end for insertion in the superior end of the medullary cavity of the humerus and a proximal end for engagement with a humeral head;

a head for positioning in a glenoid cavity, the head having, on one side, a generally spherical surface formed about an axis and, on the other side, a generally flat face bounding the spherical surface[.]; [with]

a bore [being] formed in the flat head face, the bore including an axis which is non-coaxial with the axis of the head;

a connecting member for connecting the head and stem, the connecting member having a first portion and a second portion, the first portion configured for insertion into the bore of the head, insertion of the first portion into the bore of the head achieving a first degree of eccentricity, the second portion being non-coaxial with and extending from the first portion, wherein the first portion of the connecting member is configured for rotatable insertion in the axial bore of the humeral head to enable adjustment of the second portion of the connecting member with respect to the axis of the spherical portion, thereby providing a second degree of eccentricity; and

a locking member [piece] for locking the connecting member non-rotatably within the bore.

9. The prosthesis of claim 1 wherein the locking member includes a tool-engaging [too-engaging] surface for receiving a tool for adjusting the locking member.



**VERSION WITH MARKINGS TO SHOW CHANGES
MADE TO THE SPECIFICATION**

MODULAR HUMERAL HEAD WITH ECCENTRIC CONNECTOR

FIELD OF THE INVENTION

The present invention relates to shoulder prostheses. More particularly, the present invention relates to a modular humeral head with eccentric connector that allows the modular humeral head to be connected to a humeral stem with varying
5 degrees of eccentricity.

BACKGROUND OF THE INVENTION

During the procedure of a shoulder replacement operation, at least a portion of the proximal section of the humeral shaft will be replaced by a prosthesis. Early shoulder prostheses attempted to directly replicate the upper portion of the humerus
10 which they were designed to replace. Thus, like the natural upper portion of the humerus, they were typically unitary structures including a stem to be implanted within the humerus and a head to be positioned within the glenoid cavity of the scapula.

There are several problems with the a conventional unitary shoulder prosthesis. In order to accommodate the varying morphologies of patients, it is necessary to
15 maintain a large inventory of differently configured prostheses. Not only are prostheses with different sizes of heads and stems required but also prostheses with the head and stem configured with varying radial offsets relative to one another. These various configurations are required in each size category.

To reduce the required inventory, assorted modular prostheses have been
20 devised. A modular prosthesis generally consists of two parts: a stem that is mounted into the medullary canal of the humerus, and a head component connected in some manner to the stem. The head component replaces the bearing surface of the humeral head to allow the movement of the shoulder. Different stem sizes and head sizes in a modular prosthesis provide the surgeon with some degree of inter-operative flexibility
25 which facilitates reconstruction of the original anatomy of the patient. With a range of stem sizes and a range of head sizes available, the surgeon can choose a particular

combination to suit the anatomy of each individual without having to have a large inventory of unitary humeral prostheses.

However, individual patients may also require differing offsets between the axis of the head and the axis of the stem. For example, in one patient the posterior offset may be greater than in another patient. To meet this need, some prior art prostheses provide a plurality of connecting members for connecting the head to the stem with different offsets. Differently configured connecting members are designed to provide varying degrees of eccentricity, or offset. Thus, although prior art modular prostheses have reduced the need of an inventory of differently configured unitary prostheses, an inventory of differently configured connecting members for connecting the humeral head to the stem is still required.

Accordingly, there is a need for a modular shoulder prosthesis which allows eccentricity adjustment without requiring an inventory of connecting members.

SUMMARY OF THE INVENTION

The present invention relates to shoulder prostheses in which a humeral head, chosen to suit a patient, is attached to a stem chosen to suit the resected humerus of the patient, by means of an intermediate connecting member. The intermediate connecting member can be adjusted to vary the eccentricity of the humeral head to a portion of the connecting member attachable to the stem. Two degrees of eccentricity, preferably, are provided.

The modular humeral prosthesis generally comprises a stem to be fitted to a resected humerus, a head sized and configured to approximate the humeral head, and an intermediate connecting member for connecting the stem to the head. Preferably, a locking piece is provided to secure the intermediate connecting member to the head. The humeral head has a spherical surface formed about an axis on one side and a flat face on the opposite side. A first degree of eccentricity is provided by an opening positioned eccentrically (i.e., not centered) on the flat face of the head for receiving the connecting member. The opening is preferably a threaded, shallow bore.

The connecting member is formed of a first portion for connection with the head and a second portion for connection with the stem. A second degree of eccentricity is provided by the relationship of the second portion to the first portion. The first portion, for example, may be a shallow, round plate. The second portion, for example, a male connecting piece of substantially smaller diameter than the plate, is located non-coaxially on the plate and extends generally conically therefrom. Preferably, a locking piece is used to secure the connecting member in place in the humeral head. The locking piece, preferably, is a threaded ring that is inserted over the plate of the connecting member and threaded through the bore in the head. In securing the connecting piece to connect the head to the stem, the plate is loosely inserted into the shallow bore on the humeral head. The connecting member is rotated until the desired eccentricity of the male connecting piece to the humeral head is achieved. The locking piece is inserted and threaded in the shallow bore on the humeral head to lock the connecting member in place in the humeral head. The male connecting piece fits into the conical cavity of the stem for, e.g., a Morse taper fit.

Thus, a single connecting member may provide a great variation of eccentricity of the humeral head to a portion of the connecting member attachable to the stem. This is especially advantageous in that it allows a surgeon to customize the eccentricity of the humeral head to a patient's specific morphology without requiring an extensive inventory of modular components.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 a cross-section view of one embodiment of the present invention;

Figure 2 is a bottom view of one embodiment of the humeral head of the present invention;

Figure 3 is a cross-sectional view of one embodiment of the humeral head of the invention;

Figure 4 is a bottom view of one embodiment of the connecting member of the present invention;

Figure 5 is a side view of one embodiment of the connecting member of the present invention;

5 Figure 6 is a side view of one embodiment of the locking piece of the present invention;

Figure 7 is a top view of one embodiment of the locking piece of the present invention;

Figure 8 is a bottom view of one embodiment of the invention;

10 Figure 9 is a perspective view of one embodiment of a humeral stem of the present invention;

Figure 10 is a side view of the alignment of one embodiment the humeral stem and humeral head of the present invention;

15 Figure 11 is a top view of the humeral stem and humeral head insertion in accordance with one embodiment of the present invention;

Figure 12 is a side view of one embodiment of a humeral stem and humeral head assembly of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 In the drawing, like structures are provided with like reference numerals.

Figure 1 illustrates a cross-sectional view of a first embodiment of the present invention. A shallow bore, generally 18, is positioned non-coaxially on a flat face of humeral head 10. In one embodiment, humeral head 10 locks to a connecting member 12 by a locking piece 14. Connecting member 12 includes a first portion 15 for
25 connection with the head and second portion 16 for connection with the stem 80 (see Figures 9-12). The first portion 15 may be a shallow, generally flat, round plate. Second portion 16 is a male connecting piece, of substantially smaller diameter than the

first portion, located eccentrically on the first portion and extending generally conically therefrom. Second portion 16 preferably fits into a conical cavity 82 (see Figure 9) of the stem 80 for a Morse taper fit. Locking piece 14 locks the connecting member in place in the humeral head. Preferably, locking piece 14 is a threaded ring that is
5 inserted over the first portion of connecting member 12 and threaded through bore 18 in the head. A peripheral shoulder of the locking piece is provided to engage the first portion of the connecting member.

To secure connecting member 12 to humeral head 10, the flat round plate is loosely fit into shallow bore 18 of humeral head 10. A first degree of eccentricity is
10 achieved by rotating connecting member 12 until the desired offset of second portion 16 to humeral head 10 is achieved. To secure connecting member 12 in place in humeral head 10, locking piece 14 is inserted and threaded in shallow bore 18 on humeral head.

As seen in Figure 2, bore 18 is located eccentrically on the flat bottom surface of humeral head 10; that is, the axes of the spherical head and the bore are spaced apart.
15 Bore 18 is of relatively large diameter when compared to the second portion of the connecting member. To receive the first portion of the connecting member, bore 18 is relatively shallow. Optionally, bore 18 is threaded to engage with the locking piece to secure the connecting member in place in humeral head 10 at a desired degree of eccentricity.

20 Figure 3 shows a cross-section view of the humeral head and depicts how bore 18 may be eccentrically located in humeral head 10. Threads 30 line bore 18 for engaging with the locking member.

Figure 5 illustrates a side view of connecting member 12. As is shown in Figure 5, first portion 15 is relatively shallow while second portion 16 is relatively deep. Thus,
25 first portion 15 is configured to fit into the shallow bore of the humeral head. Second portion 16 is preferably configured for a Morse taper fit with the humeral stem. However, any configuration of the second portion that allows the second portion to engage the humeral stem may be used. For example, second portion could be of a dove-tail slot configuration To provide adjustable positioning of connecting member 12
30 within the bore while preventing undesirable movement, detent 50 is preferably provided

in addition to the locking piece. A series of receiving cavities are provided in the bore of the humeral head for engaging detent 50. Thus, connecting member 12 may be rotatably adjusted in the bore into predetermined positions.

As seen in Figure 6, locking piece 14 is of a depth such that both the first portion of the connecting member and locking piece 14 may be inserted into the shallow bore of the humeral head. The outer circumference of locking piece 14 has threads 60 for threadably engaging the bore of the humeral head. Locking piece secures the connecting member in place within the humeral head at a desired eccentricity of the second portion (for engaging the humeral stem) to the humeral head is achieved.

Figure 7 provides a top view of locking piece 14. Preferably, locking piece 14 is generally configured as a ring. However, any configuration suitable for securing the connecting member in place in the humeral head may be used. Along the inside circumference of locking piece 14 are notches 74 for engaging a tool for rotating the locking piece.

As seen in Figure 8, when the components of the invention are fit together, the second portion for engaging the humeral stem may be adjusted to be positioned centrally or eccentrically on the humeral head. Shallow bore 18 is eccentrically located on the flat face of humeral head 10 and receives first portion 15 of connecting member 12, which is generally shallow and round. Second portion 16, in this embodiment, is a generally conical piece located eccentrically upon and extending conically from first plate-like portion 15. By rotating connecting member 12 within bore 18, second portion 16 may be adjusted to be located at a desired eccentricity to humeral head 10. Preferably, locking piece 14 is fit over first portion 15 of connecting member 12 and threaded into bore 18. A tool may engage notches 74 for adjusting locking piece 14.

Thus, as is described above, the eccentricity the humeral head to a portion of the connecting member attachable to the stem may be adjusted in two different ways as provided by the connecting member. First, the bore within the humeral head is non-coaxial with the humeral head. Thus, in selecting the placement of the connecting member within the bore, a first degree of eccentricity is achieved. Second, the second portion of the connecting member is non-coaxial with the first portion of the connecting

member. Thus, by rotating the connecting member within the bore, a second degree of eccentricity is achieved.

5 While various embodiments in accordance with the present invention have been shown and described, it is understood that the invention is not limited thereto, and is susceptible to numerous changes and modifications as known to those skilled in the art. Therefore, this invention is not limited to the details shown and described herein, and includes all such changes and modifications as encompassed by the scope of the appended claims.